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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/824,793

04/14/2004

James J. Modliszewski

60310-USA

6666

7590 03/16/2009
Paul A. Fair - Patent Administration
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EXAMINER

WHITE, EVERETT NMN

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

03/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/824,793	Applicant(s) MODLISZEWSKI ET AL.	
	Examiner EVERETT WHITE	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>Jan. 21, 2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 21, 2009 has been entered.
2. Applicants' response filed January 21, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:
 - (A) Comments regarding Office Action have been provided drawn to:
 - (I) nonstatutory double patenting rejection, which is maintained for the reasons or record;
 - (II) 103(a) rejection, which is maintained for the reasons of record.
3. Claims 1-27 are pending in the case.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1 and 2 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 44 and 45 of copending Application No. 10/824,688 for the reasons disclosed on pages 2 and 3 of the Office Action mailed March 6, 2006.

6. The Examiner acknowledges Applicant's request that the nonstatutory obviousness-type double patenting rejection be held until such time as notice of patentable subject matter has been received in the application. Applicants indicated an appropriate terminal disclaimer will be filed at that time if necessary.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claims 1-17, 20, 21 and 23-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gennadios (US Patent No. 6,214,376) for the reasons disclosed on pages 4-7 of the Office Action mailed March 6, 2006.
9. Claims 18, 19 and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gennadios (US Patent No. 6,214,376) for the reasons disclosed on pages 7-9 of the Office Action mailed March 6, 2006.

Response to Arguments

10. Applicant's arguments filed January 21, 2009 have been fully considered but they are not persuasive. Applicants argue against the rejection on the ground that kappa-2 carrageenans have different properties and are structurally different from kappa-carrageenans and iota carrageenans in regard to sulfation ratios, gelling properties, and water gel strength. This argument is not persuasive because where the claimed and prior art compounds possess a close structural relationship (all the compounds are carrageenans) and a specific significant property in common (i.e., gelling property, although at different degrees) which renders the claimed compounds obvious to one skilled in the art, they are effectively placed in the public domain and unpatentable per se, even though the Applicant has discovered that they possess an additional activity. In re Mod et al. (CCPA 1969) 408 F2d 1055, 161 USPQ 281; Monsanto Co. v. Rohm & Haas Co. (DC Pen 1970) 420 Fsupp 950, 164 USPQ 556 (affd. On other grounds, 172 USPQ 323). Applicants argue that persons skilled in the art would have no reasonable expectation that kappa-2 carrageenan could be used for delivery system gel film applications. This argument is not persuasive since the Gennadios patent establishes kappa and iota carrageenan compounds being present in delivery system gel film applications and the prior art, FMC Corporation Marine Colloids Division Application Bulletin G-39 filed with the IDS dated January 21, 2009, does confirm Kappa-2 carrageenan as having properties intermediate between kappa and iota carrageenans

(see page 6, last paragraph). Applicants appear to argue that the use of the Kappa-2 carrageenan as a component of a delivery system is unexpected since kappa-2 carrageenan forms soft gels. This argument does not overcome the obviousness rejection of the claims since the soft gel property of the kappa-2 carrageenan is still a gelling property which is a significant property in common with kappa and iota carrageenans, which are known components of delivery systems. It would be obvious to a person of ordinary skill in this art having the Gennadios patent before him that kappa-2 carrageenan would be applicable in delivery system gel film applications. No unexpected properties have been noted in the instantly claimed delivery system gel film composition comprising kappa-2 carrageenan. Accordingly, the rejections of Claims 1-27 under 35 U.S.C. 103(a) as being unpatentable over the Gennadios patent are maintained for the reasons of record.

Summary

11. All the claims are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Everett White/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623